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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

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TITLE OF THE INVENTION (280 characters max)

CORDLESS INTERNAL DEFIBRILLATOR

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ENCLOSED APPLICATION PARTS *(check all that apply)*

☒ Specification *Number of Pages* 14

☒ Drawing(s) *Number of Sheets* 2

☐ Application Data Sheet. See 37 CFR 1.76

☐ CD(s), Number

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METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT

☐ Applicant claims small entity status. See 37 CFR 1.27.

☐ A check or money order is enclosed to cover the filing fees

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The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☒ No.

☐ Yes, the name of the U.S. Government agency and the Government contract number are: _____

Respectfully submitted,

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Date 2 Feb 04

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REGISTRATION NO. *(if appropriate)* 28,923

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USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

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CORDLESS INTERNAL DEFIBRILLATOR

BACKGROUND OF THE INVENTION

The present invention relates to medical devices that are used to provide emergency cardiac care for conditions during open-heart surgery. More particularly, the present invention relates to internal defibrillators and their means for delivering electrical energy to a patient during surgery.

There are many different types of defibrillators on the market today, but they all can be classified in one of two categories; external and internal defibrillators. External defibrillators, which include types requiring little sophistication from the user, such as Automatic External Defibrillators, are beginning to be located in public places such as theatres and shopping centers in order to save lives. External defibrillators are applied to the patient topically, i.e., through the skin, whereby a pulse applied to the patient travels through the skin, the thorax tissue, and then to the heart.

However, internal defibrillators are designed for use particularly during open-heart surgery. During such surgery, it is a common practice that the heart is prevented from beating (with the person being hooked up to a life-support heart-bypass machine) so that the surgeons can operate on the heart. After the surgeons have repaired/removed whatever was causing the problem, an internal defibrillator is applied directly onto the heart to jump-start its beating. This defibrillation is performed by the surgeon using two special internal-defibrillation-paddle electrodes, wherein the surgeon inserts the internal paddle electrodes into the patient's open chest to restart the heart. The electrode paddles must be sterile to avoid contaminating/infecting the heart. Normally, the surgeon holds one paddle in each hand and places the two electrodes against opposite sides of the heart so that an electrical discharge is passed from one electrode through the heart to the second electrode.

The electrical discharge is currently supplied from a large general-purpose defibrillator. Since the defibrillator is not sterile, it must be placed outside the sterile operating

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field and located some distance from the patient. The paddles are connected to the defibrillator by long cables draped from the defibrillator to the patient's open chest. One cable is connected to each paddle electrode.

The conventionally-used cables and electrodes suffer from at least the following problems. Two people are required to set up the internal defibrillator for use during an operation. First, a "sterile" person is required to prepare the sterile electrode paddles in a sterile field of the operating room. However, the location of the defibrillator is outside the sterile field. A second "non-sterile" person is required to receive the cable connector from the "sterile" person and connect it to the defibrillator.

The long cables draped from the defibrillator to the patient's open chest need to be large and bulky to be able to deliver a high voltage shock to the patient. Shocks as high as 1,000 volts and exceeding 50 amps at discharge require the cable to be large, hard to handle, and prone to tangle. The cables are also bulky in order to protect the user from shock, as defibrillators of this type having electrical discharges as high 1,000 volts require the cable insulation to be relatively thick, thus limiting the cable flexibility.

The consequences of having such big, bulky cables fed from across the room from a non-sterile area are numerous. These cables can interfere with the placement of the electrode paddles, and are a common failure point. In addition, the cables invariably get in the way of the surgeon during an operation, impeding the entire operating room. Moreover, the cables themselves, as well as the cable connections, are often common points of failure in the system.

The internal paddles/cables of a conventional defibrillator are not interchangeable with different defibrillators, meaning that the hospitals must keep spares for each machine that requires a lengthy replacement process by qualified personnel. Finally, as there are two separately-held electrode paddles (one in each hand) there is an operator safety issue looming

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because there is always a possibility that the operator may inadvertently shock him/herself with one of the paddles.

Thus, a need exists for an improvement in the defibrillator's delivery of electrical shock to the patient.

The present invention overcomes many of the aforementioned problems of conventional internal defibrillators. According to the present invention an optimized cordless defibrillator is built into the handles of the paddle electrodes, thereby eliminating all the problems and limitations of using thick bulky cables. Moreover, this arrangement eliminates the need for the general-purpose defibrillator to be placed in an area outside the sterile field. No longer is it necessary to have two people set up the defibrillator and cables for use.

In the present application, the term "paddle" is used throughout. For purposes of this application, it is to be understood by an artisan that the term paddle refers to the handle, shaft, and electrode. Additionally, an internal defibrillator comprises a paddle along with the electronics necessary to administer a therapeutic shock being arranged within one or more paddles.

The cordless defibrillator eliminates the heavy, inflexible cables of conventional internal-defibrillator systems that get in the way of the doctors and nurses, and/or get tangled up and require untangling when time could be critical. A common point of failure is also eliminated, and the possibility of contamination is decreased as the entire unit can be located in the sterile field.

According to one aspect of the present invention, the two paddles can be controlled by a single-handle that is held and used with only one hand, increasing the potential accuracy and safety of the invention as compared with holding each paddle by a separate handle, as the single-handle does not require separate placement in the patient's chest to administer the shock. A predetermined distance between the electrodes can be adjusted by a regulator arm prior to inserting the paddles into the patient's chest, and then the paddles can be placed more

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accurately in the patient to administer the shock across the desired portions of the heart by the operator holding a single handle, rather than two independent handles.

According to another aspect of the present invention, some or all of the internal defibrillator components may be disposable, thus eliminating the need for cleaning and sterilizing between procedures.

According to still another aspect of the present invention, the defibrillator preferably has eliminated some non-essential equipment that is commonly used with conventional internal defibrillators. Some of these items may include:

(1) Limiting the discharge energy to less than 50 Joules;

(2) Eliminating any ECG amplifiers;

(3) Eliminating any waveform or parametric display;

(4) Eliminating any waveform analysis or recording; and/or

(5) Powering the device with reusable or disposable batteries.

The elimination of these items optimally allows for a compact, lightweight, internal cordless defibrillator that eliminates the need to keep a conventional defibrillator in the operating room beyond a safe point (due to the fact that the instrument is not sterile) and running long bulky cables to the paddles.

Fig. 1 illustrates a first aspect of the present invention, wherein a cordless internal defibrillator utilizes paddles that are controlled by a single handle.

Fig. 2 illustrates a second aspect of the present invention, wherein a cordless internal defibrillator utilizes paddles that are controlled by two separate handles that can be separated or locked at a certain desired distance between the electrodes so as to operate as a single unit.

Fig. 1 illustrates a first aspect of the present invention. This particular illustration is a "one-handed design" but it should be understood that a two-handed design may also be used. In either case the defibrillator circuitry is self-contained in the paddles or the handle. The internal defibrillator includes a pair of electrodes (105) that are adapted for internal

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application to the heart, i.e., to shock the heart when the chest cavity is open, such as during open-heart surgery. The electrodes (105) are arranged respectively at end portions of a pair of paddles (107a, 107b). At least one of the paddles (107a, b) is pivotable relative to the other via pivot (108) so that the distance between the electrodes (105) can be varied. As different patients may have different sized hearts (including children), the ability to adjust the spread of the paddles permits greater flexibility than does a stationary distance.

Attached to the pivot (108) is a handle (109) that can be similar in size and shape to the handles on other hand-held tools, such as a power drill, or even a handgun. Arranged inside the handle are a control circuit (110), an energy-storage facility (111), and a power supply (112). The handle (109) is also adapted to receive a battery by arranging positive and negative contacts in a battery compartment (112a). Power from the battery compartment (112a) is fed to the power supply (112), and in turn the power supply supplies the energy for logic of control circuit (110) and the energy-storage facility (111). Optionally, there can be a dial and/or selection control switches (115) that are used to provide different charge settings to the patient. There is also a discharge switch (118) which the user pulls or presses, similar to a trigger on a handgun, so as to administer the electrical impulse.

A regulator arm (114) is attached to at least one of the paddles via the pivot and is biased so that the electrodes (105) are a predetermined distance apart. It is preferable that a locking mechanism or spring (116) retains the regulator arm (114) at a desired position so as to lock-in a desired distance between the electrodes (105).

The regulator arm may comprise part of an end of one of the paddles, or it could be a separate piece of material that can be used to adjust the bias or leverage applied to at least one of the paddles, so as to cause it to move. Preferably, the handle is made of an insulating material, or at least has an insulating coating arranged thereon. The user pushes the regulator handle (114) either toward or away from the handle (109) to vary the distance between the electrodes, so that the present invention can be used with patients of different ages and sizes

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(from children through geriatrics). Finally, it should be noted that the defibrillator may have automatic features, wherein once activated the unit determines whether and to what extent the heart should be shocked.

Fig. 2 illustrates a second embodiment of the present invention. This drawing shows an internal defibrillator with a dual-handle design, as opposed to the single-handle design shown in Fig. 1.

The electrodes (205) are respectively attached to one end a pair of paddles (207a, 207b). The paddles are connected to the respective left and right handles (209a, 209b). The left and right handles are electrically connected by at least one wire (210). It should be noted that any flexible conductor and/or flex board could provide a conduction path. Optionally, the handles (209a, 209b) can be arranged on a slidable track (213) which allows the electrodes (209a, 209b) to be spaced according to need. The track may have a locking mechanism (215) to hold the handles (and thus the electrodes) at the desired distance from each other. This locking mechanism could be a latch, or a wingnut and a bolt that can travel within a slot cut into the track, a hook, or any known type of lock device that a user can both lock and/or release quickly.

It should be noted that while the two-handle design contemplates one hand per handle, once the distance between the electrodes is locked at the track (213), only a single handle needs to be held, as the distance between the electrodes is fixed. Moreover, one could hold onto one of the handles and use the other hand to activate the shock to the patient after the device is arranged in proper position within the patient.

Arranged within the dual-handle design are the complete defibrillation circuitry, including a battery (214), a power supply (216), a storage unit (218), and a control circuit (220). It is contemplated that a battery would be arranged in the power-receiving unit. Optionally, there may also be a ready light (222) arranged on one of the handles to indicate when the defibrillator is ready for use. Similar to the controls (115) on the defibrillator shown

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in Fig. 1, the dual-handle design will also have a switch or knobs to control the amount and/or duration of the electrical impulse to be applied to the patient. The defibrillator may also have automatic features, wherein once activated the unit determines whether and to what extent the heart should be shocked.

In either embodiment of the present invention the arrangements provide a clutter-free defibrillator that allows easier use because of the lack of cables that are required by conventional internal defibrillators, improving the control of the unit, particularly the ability to maneuver the paddles into position. Several failure points are eliminated by arranging the circuitry within the handles/paddles. In the case of both a single handle and two-handle design, operator safety is improved as the internal defibrillator has no cables and is therefore tangle-free. Also, in both embodiments, some or all of the internal-defibrillator components can be used for a single patient and then thrown away. The disposability can eliminate the need to sterilize internal-defibrillator components, such as the paddle or electrodes, and thus reduce potential infection problems that could occur if, for example, the paddle is not sterilized properly.

Since the internal defibrillator is self-contained, yet another aspect of the invention can be to limit the discharge energy to less than 50 joules. While this energy discharge amount is optional, there will be a savings in size and power if such a limit is utilized. In addition, more power is saved and the unit can be made even lighter by eliminating items such as ECG amplifiers, the parametric display of a waveform or the analysis and/or recording of the waves. The device may be powered with reusable or disposable batteries.

A method of providing a single-handle internal defibrillator includes the steps of:

(a) attaching the pair of electrodes to first-end portions of the pair of paddles, respectively;

(b) connecting a second-end portion of the pair of paddles to a single handle, with at least one paddle of the pair of paddles being movable with respect to the other;

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(c) providing an adjustment such as a regulator arm to adjust the movement so that the distance between the electrodes is variable; and,

(d) arranging internal-defibrillator circuitry to be within the single handle.

Thus, the present invention eliminates the usage of large bulky cables that interfere with movement of the surgeons and nurses, reduces potential contamination issues by the need to arrange a defibrillator in a non-sterile field and then drape the cables back into the sterile field, reduces potential safety issues with the single-handle model, allows for setting the distance between the electrodes to permit more accurate placement of the electric shock, eliminates the need for two people to set up the defibrillator and cables, and eliminates the need for the general-purpose defibrillator in the operating room.

It should be understood that various modifications can be made by persons of ordinary skill in the art once they have gleaned the knowledge of the present invention, and such changes will lie within the spirit of the invention and the scope of the appended claims. For example, the shape of the electrodes, the shape of the paddles, the appearance of the single-handle and dual-handle may be changed in both size and shape. There can be, for example, other items in the defibrillation circuitry other than what is shown, so long as they are arranged within the handle of the device. The lock mechanism can be any known type of lock, so long as it serves the purpose of locking. Some or all of the components of the internal defibrillator may be disposable, for example, such as the paddle or just the electrodes, and the paddle may take any known shape according to need.

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What is claimed is:

1. A single-handle cordless defibrillator, comprising:

a pair of paddles that includes a pair of electrodes (105) respectively connected to a first-end portion of the pair of paddles;

the pair of paddles having a second end portion in communication with a single-handle, with at least one paddle of the pair of paddles being pivotable about a pivot arranged between the at least one paddle and the single-handle;

a regulator arm in communication with the pivot for adjusting the pivot of at least one paddle about the pivot so that a distance between the electrodes is variable by moving the regulator arm; and

defibrillator circuitry arranged completely within the single-handle.

2. The defibrillator according to claim 1, further comprising:

a locking mechanism or spring that retains the regulator arm at a desired position so as to maintain a desired distance between the electrodes.

3. The defibrillator according to claim 1, wherein the plurality of defibrillator circuitry includes a power supply.

4. The defibrillator according to claim 1, wherein the defibrillator circuitry includes an energy storage unit.

5. The defibrillator according to claim 1, wherein the defibrillator circuitry includes a control circuit.

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6. The defibrillator according to claim 1, wherein the defibrillator circuitry includes a power supply.

7. The defibrillator according to claim 1, further comprising a discharge switch that is arranged at least partly within the single-handle.

8. The defibrillator according to claim 5, further comprising a discharge switch that communicates with the control circuit to initially request a shock to a patient.

9. The defibrillator according to claim 1, further comprising a control switch that is adapted for a user to vary the amount, duration, and type of electrical impulse applied to a patient.

10. The defibrillator according to claim 1, wherein the defibrillator comprises an internal defibrillator having electrodes adapted for applying a shock internally to a patient's heart.

11. The defibrillator according to claim 10, wherein at least some of a plurality of components of the internal defibrillator are disposable after being used on a single patient, and a maximum energy applied for internal defibrillation comprises less than 50 Joules.

12. A dual-handle cordless defibrillator comprising:

a pair of paddles including a pair of electrodes attached respectively to a first-end portion of the pair of paddles;

the pair of paddles each having a second-end portion connected respectively to one of dual-handles, respectively;

a conductor for electrically connecting the dual-handles; and,

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a defibrillator circuitry arranged within the dual-handles.

13. The defibrillator according to claim 12, further comprising:

an adjustable track that is attached to the dual-handles to adjust a distance between the electrodes by adjusting a distance between the dual-handles.

14. The defibrillator according to claim 13, further comprising:

a locking mechanism or spring that locks the dual-handles to the adjustable track at a predetermined position so as to fix the distance between the electrodes.

15. The defibrillator according to claim 12, wherein the defibrillator circuitry further comprises a power supply.

16. The defibrillator according to claim 12, wherein the plurality of defibrillator circuitry includes an energy storage unit.

17. The defibrillator according to claim 12, wherein the plurality of defibrillator circuitry includes a control circuit.

18. The defibrillator according to claim 12, wherein the defibrillator circuitry includes a power supply.

19. The defibrillator according to claim 12, wherein the electrodes are adapted for providing internal defibrillation.

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20. The defibrillator according to claim 12, wherein the conductor comprises a flexible circuit board.

21. A method of providing a single-handle cordless defibrillator, comprising the steps of:

(a) attaching a pair of electrodes respectively to a first-end portion of the pair of paddles;

(b) connecting a second-end portion of the pair of paddles to a single handle, with at least one paddle of the pair of paddles being movable about a pivot arranged between the one paddle and the single handle; and,

(c) providing a regulator arm to adjust the pivot of at least one paddle about the pivot so that a distance between the electrodes is variable by moving the regulator arm; and,

(d) arranging defibrillator circuitry completely within the single handle.

22. The method according to claim 21, further comprising (e) providing a locking mechanism to keep the regulator arm at a desired position so as to lock-in a desired distance between the electrodes

23. A method of providing a dual-handle cordless defibrillator comprising the steps of:

(a) attaching a pair of electrodes respectively to a first-end portion of a pair of paddles;

(b) connecting a second-end portion of each paddle of the pair of paddles to one of dual-handles, respectively;

(c) electrically connecting the dual-handles; and,

(d) arranging defibrillator circuitry within the dual-handles.

24. The method according to claim 23, further comprising:

(e) providing an adjustable track that attaches to the dual-handles to adjust a distance between the electrodes by adjusting the distance between the dual-handles.

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25. The method according to claim 24, further comprising:

(f) providing a locking mechanism for the adjustable track to fix the distance between the electrodes at a desired distance.

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ABSTRACT OF THE DISCLOSURE

A single-handle cordless internal defibrillator includes a pair of paddles, and a pair of electrodes that are respectively connected to a first-end portion of the pair of paddles. The pair of paddles has a second-end portion in communication with a single-handle, with a least one paddle of the pair of paddles being pivotable about a pivot arranged between the one paddle and the single-handle. A regulator arm in communication with the pivot adjusts the pivot of at least one paddle about the pivot so that the distance between the electrodes is variable by moving the regulator arm, and defibrillator circuitry is arranged within the single-handle. A dual-handle structure also provides tangle-free and clutter-free applications as the defibrillator circuitry is self-contained in the handle/handles or paddles of the defibrillator, eliminating the need for long cables which obstruct and can contaminate an operating room.

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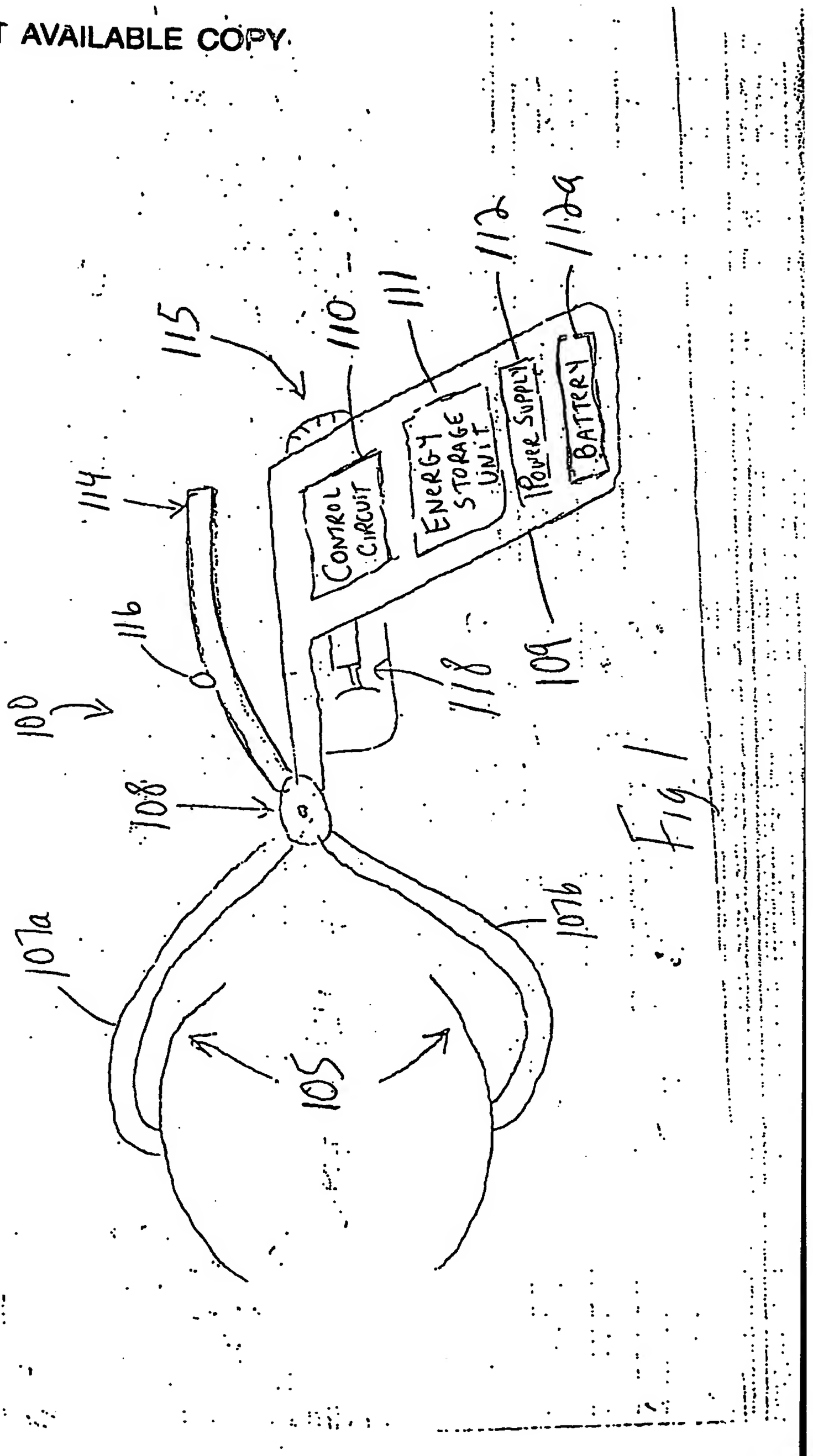

Fig 1

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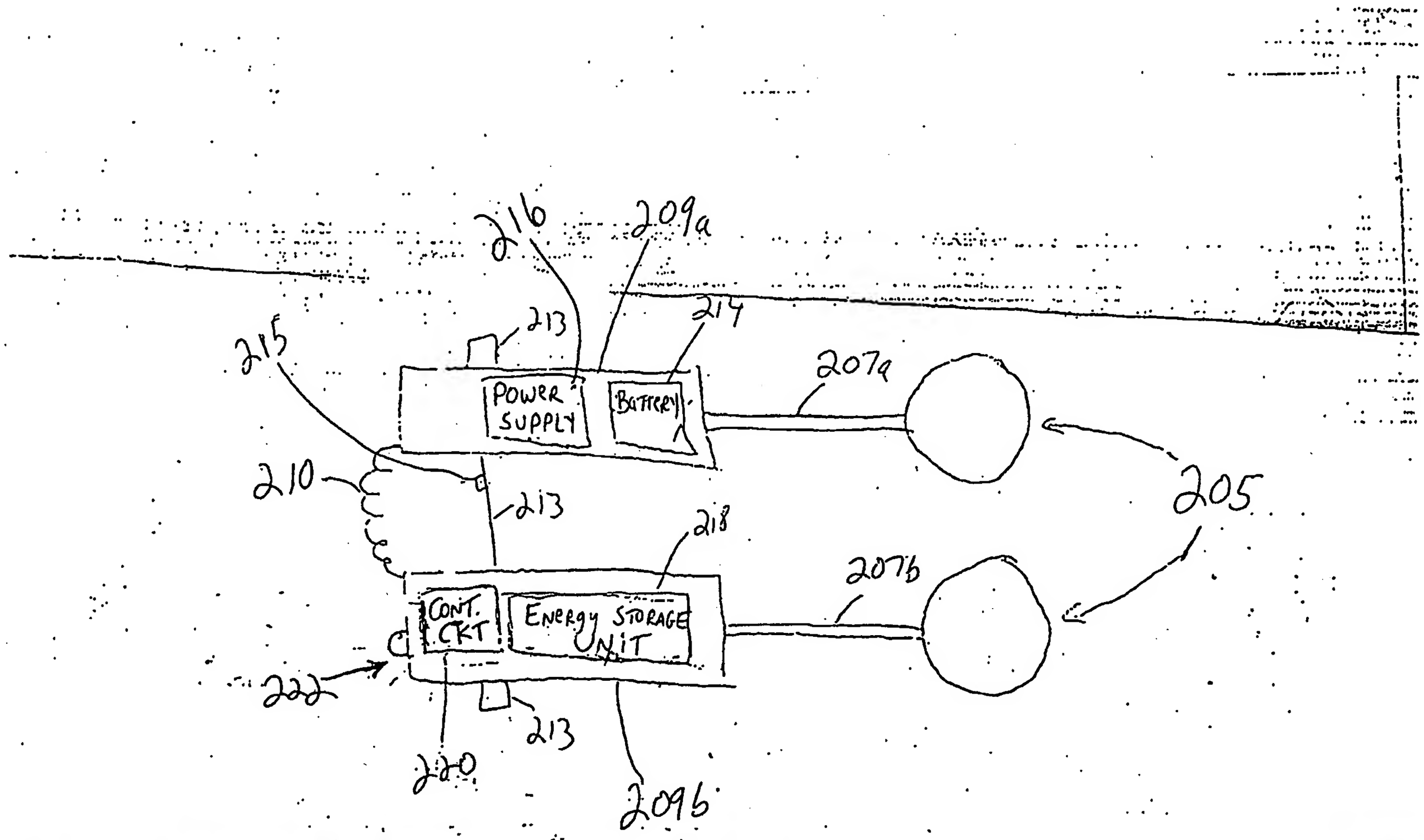

Fig. 2

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